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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,378	10/12/2001	Chad A. Mirkin	00-713-i25	2333

7590 03/12/2003

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EXAMINER

RILEY, JEZIA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/12/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,378

Applicant(s)

MIRKIN ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 431-432 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 431 and 432 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The disclosure is objected to because of the following informalities: The continuation data in the specification are incomplete.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 431-432 are rejected under 35 U.S.C. 102(e) as being anticipated by Ygueralbide et al. (6,214,560).

Ygueralbide et al. discloses a method for the detection and measurement of one or more analytes in a sample. The method is based on the use of certain particles of specific composition, size, and shape and the detection and/or measurement of one or more of the particle's light scattering properties. The detection and/or measurement of the light-scattering properties of the particle is correlated to the presence, and/or amount, or absence of one or more analytes in a sample. The present invention is versatile and has utility in one form or another to detect and measure one or more analytes in a sample. One or more analytes in a sample can be detected and measured by detection and/or measurement of one or more of the specific light scattering properties of metal-like particles. (Summary of the Invention). For example, a certain nucleic acid analyte is composed of about 100 nucleic acid bases and is present in a sample. The sample is prepared so that this nucleic acid is in a single stranded form. Then two or more unique single-stranded "probe" nucleic acid sequences are added to the sample where these different probes bind to different regions of the target strand which is viewed to be inclusive of the separating method of the instant application. Each of these probes has attached to one or more particles (col. 74). Further, the particles can form different types of aggregates that can be detected

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visually or instrumentally in a microscope or through macroscopic observation or measurements without having to separate free from analyte bound particles.. The method provides for useful apparatus and particle types for specific test kits can be constructed. These different test kits, and associated apparatus are useful for applications to consumer use, portable field use, point of care applications such as doctor's offices, clinics, emergency rooms and the

The particle has a size, composition and shape suitable for producing specific light scattering signal(s) of specific wavelength(s), color(s), polarization, angular dependence, and RIFSLIW of the scattered light that is detectable by eye or photodetector means; the detection includes the methods of counting the particles, and/or measurement of the intensity of scattered light as a measurement of the concentration of the particles; the particle is formed from metal-like materials or is formed from a mixed composition including non-metal-like materials, the particles are spherical, oval, or asymmetrical; the particles are coated with binding agents, polymers, reactive chemical groups, base material molecules, inorganic and organic compounds; the change in scattered light properties when two or more particles are brought into close contact with each other in assay formats is used; particle reagents comprised of metal-like material and coated with base material molecules adapted to bind to a binding agent are used; assay formats wherein two or more particles are brought sufficiently close together so that the light scattering property of the two or more particles can be resolved from single particles is used; assay formats wherein two or more particles that are held in close proximity to one another are caused to be

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separated so that the light scattering property of any one particle is altered is used; assay formats wherein two or more particles are linked together by one or more molecular interactions such that when the molecular interaction holding the particles together is disrupted, one or more particles are released from the molecular interaction is used; assay formats wherein the amplified detection of analytes is accomplished by cross-linking two or more particles together using chemical or biological cross-linking agents is used; the particles are composed of additional materials to allow them to be oriented in an electric, magnetic or related electromagnetic field (EMF); the particles are attached to other particles of magnetic or ferro-electric properties; and the illuminating light beam has a wavelength selected to reduce background as compared to other wavelengths.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 431-432 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 431 and 432 depend from canceled claims which make them confusing.

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Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 431-432 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 189 of copending Application No. 09/976,971. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common embodiments but not of the same scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855.

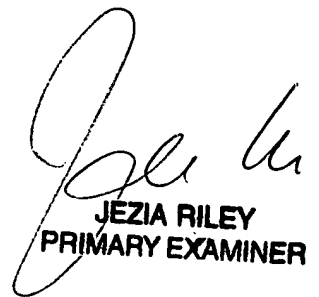
The examiner can normally be reached on 9:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

February 24, 2003



JEZIA RILEY
PRIMARY EXAMINER